

U.S. Patent Application Serial No. 10/743,546  
Amendment filed January 20, 2006  
Reply to OA dated August 24, 2005

### **REMARKS**

Claims 1-6 are pending in this application. Claim 1 has been amended herein. Upon entry of this amendment, claims 1-6 will be pending. Entry of this amendment and reconsideration of the rejections are respectfully requested.

No new matter has been introduced by this Amendment. Support for the amendment to the claims is discussed below.

**The rejection of claims 1-6 under 35 U.S.C. §103(a) as being obvious over Ehara, T. et al. (JP 2002-355030) is maintained for the reasons set forth in the previous Office Action on page 2. (Office Action paragraph no. 1)**

To avoid confusion, Applicant notes that the author of JP 2002-355030 is actually “Gaku Ehara”, not “Takeshi Ebara” as listed on the Patent Abstracts of Japan abstract. The discrepancy is due to a mistranslation in the PAJ abstract. The reference will be referred to as Ehara et al. JP '030.

The rejection of claims 1-6 is respectfully traversed, and reconsideration of the rejection is requested.

In traversing the rejection, Applicant maintains the argument that the medium disclosed in JP '030 does not meet the limitation of “0.1 to 0.7% by weight of proline” in claim 1.

The Examiner cites several teachings of the reference, in particular paragraph [0021], which indicates that proline is present in “usual culture media”:

“The Examiner interprets this section of the prior art to imply that as glutamic acid,

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as is proline and the other 14 amino acids, are a source of nitrogen. Since the above mentioned amino acids are of the same source **it would be possible** to use the same weight needed for glutamic acid as for proline.” (emphasis added)

Applicant submits that this argument by the Examiner does not provide a proper *prima facie* case of obviousness. Note that MPEP 2142 states:

“To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must be found in the prior art, and not based on applicant’s disclosure.”

The Examiner's argument that “it would be possible” at best argues only that the present invention is enabled; that is, one of skill in the art could make a medium as in claim 1. However, the Examiner has not provided any suggestion or motivation in the reference for the use of proline at the levels disclosed in JP'030 for glutamic acid.

Ehara et al. JP '030 simply discloses that the medium contains 0.2-4.0% by weight of glutamic acid. However, each amino acid is a different chemical species, and it is general knowledge in biochemistry that different amino acids are **not interchangeable**. Supplementation of a medium with glutamic acid as in JP '030 does not suggest supplementation with proline at the same levels.

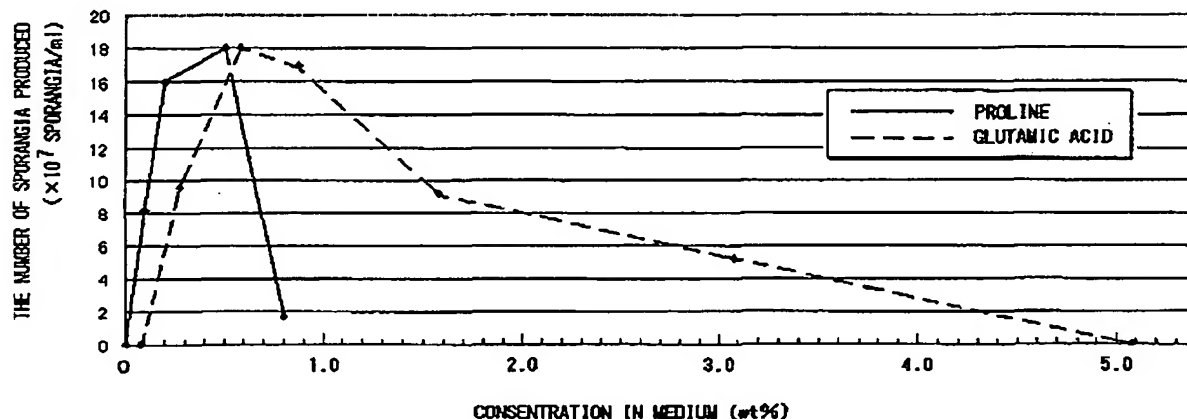
Moreover, there is no indication in Ehara et al. JP '030 that the proline is present as anything other than a nutrient source. Therefore, there is no suggestion in the reference or in the general art to increase the proline level above what is disclosed in the reference.

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However, in the specification of the present application, it is demonstrated that when proline is used in a higher concentration, it has enhancing effects on sporangia production. The effects were not exhibited when alanine is used (see Tables 5 and 7 of the present application). There is no disclosure of this in Ehara et al. JP'030, and paragraph [0021] of Ehara et al. JP '030 cannot be taken as suggesting a higher proline concentration.

With regard to the disclosure of 16 kinds of amino acids in the reference, Ehara et al. JP'030 simply states that these amino acids are found in peptone, meat extract, fish extract, lactoalbumin hydrolyzates, and yeast extract; and that such amino acids can be used as nitrogen sources. Therefore, the citation neither teaches nor suggests that such amino acids are included in the growth medium with their concentration being adjusted to the level higher than the usual level so as to enhance the sporangia production. There is no motivation in the reference to increase the concentration of proline to achieve the effects unique to the present invention.

In addition to the above arguments regarding the *prima facie* case of obviousness, it is also clear that the fact that the proline concentration required to achieve a certain level of enhancement of sporangia production is lower than the concentration required for glutamic acid to achieve the similar level of effects, is unexpected over the reference. The following graph is prepared by superposing the data of Table 3 of JP '030 on those of Table 2 of the present application.



As shown in this graph, the peak for proline appears in a lower concentration than the peak for glutamic acid. More specifically, in order to obtain  $16 \times 10^7$ /ml of sporangia, approximately 0.20-0.55% by weight of proline is sufficient; while to achieve the similar effects, approximately 0.50-0.95% by weight of glutamic acid is required. In other words, only about half the concentration is required for proline.

Claims 1-6 are therefore not obvious over (JP 2002-355030).

**Claims 1-6 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. (Office Action paragraph no. 2)**

The Examiner now states that the claims do not recite "positive active method steps."

The rejection is overcome by the amendment to claim 1. Claim 1 has been amended to positively recite steps by inserting the phrase --comprising the step of--, in place of the word "by".

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Applicant submits that this amendment is for grammatical clarity only, and is fully supported by the recitation of claim 1 before the amendment.

**Claims 1-4 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 2005/0123518 A1 [sic]. (Office Action paragraph no. 3)**

To avoid confusion, Applicant notes that the Examiner incorrectly refers to U.S. Application No. 10/730,258, by its publication number, 2005/0123518.

The obviousness-type double patenting rejection of claims 1-4 is respectfully traversed, and reconsideration of the rejection is requested.

Applicant notes that claim 1 of USSN '258 (as published) reads:

1. A process for producing sporangia of *Bacillus popilliae* containing spores and parasporal bodies comprising the step of culturing *Bacillus popilliae* in a medium containing an adsorbent and 0.2-4.0% by weight of glutamic acid.

There is no recitation in any of claims 1-4 of USSN '258 regarding the proline content of the culture medium. There would therefore appear to be no explicit disclosure or suggestion in the claims of USSN '258 for the proline content limitation of present claim 1.

The Examiner refers to the disclosure in paragraph [0029] of the publication of USSN '258, that proline is one of 16 amino acids known to be contained in nitrogen sources such as peptones and yeast extract. The Examiner therefore infers that there would be some proline in the culture medium. This amount of proline would not meet the limitation of present claim 1.

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Applicant respectfully disagrees with the Examiner's contention that "It would have been obvious ... to substitute one amino acid for another". The Examiner is taking the disclosure of USSN '258 of 0.2-4.0% of glutamic acid, and stating that proline could have been used instead of glutamic acid.

However, the level of 0.2-4.0% of glutamic acid is used in USSN '258 for reasons stated in the reference, and only glutamic acid is disclosed in this regard.

Moreover, as discussed above, it is well known in the art that each amino acid is a different chemical substance, and amino acids are generally not interchangeable biologically. There is no suggestion in the reference or the general art to supplement the medium in USSN '258 with such levels of proline.

Claims 1-4 are therefore not obvious over claims 1-4 of USSN '258.

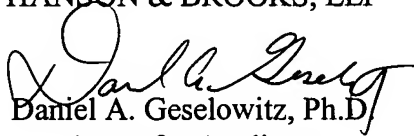
If, for any reason, it is felt that this application is not now in condition for allowance, the Examiner is requested to contact the Applicant's undersigned agent at the telephone number indicated below to arrange for an interview to expedite the disposition of this case.

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In the event that this paper is not timely filed, the Applicant respectfully petitions for an appropriate extension of time. Please charge any fees for such an extension of time and any other fees which may be due with respect to this paper, to Deposit Account No. 01-2340.

Respectfully submitted,

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PATENT TRADEMARK OFFICE

Enclosure: Petition for Extension of Time

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